

EXHIBIT B

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN AND)
)
IRBESARTAN PRODUCTS LIABILITY)
) CASE NO:
LITIGATION) 1:19-md-02875-RBKJS
)
)
THIS DOCUMENT RELATES TO:)
In Re: Valsartan, Losartan and)
Irbesartan Products Liability)
Litigation.)

(VOLUME II)

HIGHLY CONFIDENTIAL REMOTE VIDEOTAPED DEPOSITION
OF LAURA M. PLUNKETT, Ph.D.
FRIDAY, FEBRUARY 10, 2023
9:04 CENTRAL TIME

<p style="text-align: right;">Page 337</p> <p>1</p> <p>2 TRANSCRIPT of the stenographic notes of</p> <p>3 the proceedings in the above-entitled matter, as</p> <p>4 taken by and before LYDIA F. McDONNELL, a Certified</p> <p>5 Shorthand Reporter and Notary Public of the State of</p> <p>6 New Jersey, held remotely from Houston, Texas, on</p> <p>7 Friday, February 10, 2023, commencing at 9:04 a.m.</p> <p>8 Cental Time</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 339</p> <p>1 A P P E A R A N C E S: (Continued)</p> <p>2 (All appearances remote via Zoom conference.)</p> <p>3 HINSHAW & CULBERTSON LLP</p> <p>4 BY: GEOFFREY M. COAN, ESQ.</p> <p>5 53 State Street, 27th Floor</p> <p>6 Boston, Massachusetts 02109</p> <p>7 617-213-7000</p> <p>8 gcoan@hinshawlaw.com</p> <p>9 Attorneys for the Defendant,</p> <p>10 Sciegen Pharmaceuticals, Inc.</p> <p>11</p> <p>12 HILL WALLACK LLP</p> <p>13 BY: WILLIAM P. MURTHA, JR., ESQ.</p> <p>14 21 Roszel Road</p> <p>15 Princeton, New Jersey 08540</p> <p>16 609-924-0808</p> <p>17 wmurtha@hillwallack.com</p> <p>18 Attorneys for the Defendant,</p> <p>19 Hetero Labs and Hetero Drugs</p> <p>20</p> <p>21 GREENBERG TRAURIG, LLP</p> <p>22 BY: STEVEN M. HARKINS, ESQ.</p> <p>23 Terminus 200</p> <p>24 3333 Piedmont Road NE, Suite 2500</p> <p>25 Atlanta, Georgia 30305</p> <p>678-553-2312</p> <p>sharkins@gtlaw.com</p> <p>Attorneys for the Defendant,</p> <p>Teva Pharmaceutical USA, Inc.</p> <p>-and-</p> <p>WALSH PIZZIZI O'REILLY FALANGA, LLP</p> <p>BY: CHRISTINE I. GANNON, ESQ.</p> <p>Three Gateway Center</p> <p>100 Mulberry Street, 15th Floor</p> <p>Newark, New Jersey 07102</p> <p>973-751-1017</p> <p>cgannon@walsh.law</p> <p>Attorneys for the Defendant,</p> <p>Teva Pharmaceutical USA, Inc.</p> <p></p> <p></p> <p></p>
<p style="text-align: right;">Page 338</p> <p>1 A P P E A R A N C E S:</p> <p>2 (All appearances remote via Zoom conference.)</p> <p>3 HOLLIS LAW FIRM, P.A.</p> <p>4 BY: C. BRETT VAUGHN, ESQ.</p> <p>5 8101 College Boulevard, Suite 260</p> <p>6 Overland Park, Kansas 66210</p> <p>7 913-385-5402</p> <p>8 brett@hollislawfirm.com</p> <p>9 Attorneys for the Plaintiffs</p> <p>10 - and -</p> <p>11 LEVIN PAPANTONIO RAFFERTY PROCTOR BUCHANAN</p> <p>12 O'BRIEN BARR MOUGEY, P.A.</p> <p>13 BY: DANIEL NIGH, ESQ.</p> <p>14 316 S Baylen Street</p> <p>15 Pensacola, Florida 32502</p> <p>16 805-435-7000</p> <p>17 dnigh@levinlaw.com</p> <p>18 Attorneys for the Plaintiffs</p> <p>19 - and -</p> <p>20 RIVERO MESTRE LLP</p> <p>21 BY: JORGE MESTRE, ESQ.</p> <p>22 -and-</p> <p>23 ZALMAN KASS, ESQ.</p> <p>24 2525 Ponce de Leon #1000</p> <p>25 Miami, Florida 33134</p> <p>305-445-2500</p> <p>jmestre@riveromestre.com</p> <p>zkass@riveromestre.com</p> <p>Attorneys for the Plaintiffs</p> <p>- and -</p> <p>HARDING MAZOTTI, LLP</p> <p>BY: ROSEMARIE RIDDLE BOGDAN, ESQ.</p> <p>100 Park Avenue</p> <p>New York, New York 10017</p> <p>917-540-9803</p> <p>Rosemarie.bogdan@1800law1010.com</p> <p>Attorneys for the Plaintiffs</p> <p></p> <p></p> <p></p>	<p style="text-align: right;">Page 340</p> <p>1 A P P E A R A N C E S: (Continue)</p> <p>2 (All appearance remote via Zoom conference.)</p> <p>3 SKADDEN, ARPS, SLATER, NEAGHER & FLOM, LLP</p> <p>4 BY: JESSICA D. MILLER, ESQ.</p> <p>5 One Manhattan West</p> <p>6 New York, New York 10001-8602</p> <p>7 212-735-2588</p> <p>8 jessica.miller@skadden.com</p> <p>9 Attorneys for the Defendant,</p> <p>10 ZHP</p> <p>11</p> <p>12 PIETRAGALLO GORDON ALFANO BOSICK & RASPANTI, LLP</p> <p>13 BY: JASON M. REEFER, ESQ.</p> <p>14 -and-</p> <p>15 FRANK H. STOY, ESQ.</p> <p>16 301 Grant Street, 38th Floor</p> <p>17 Pittsburgh, Pennsylvania 15219</p> <p>18 jmr@pietragallo.com</p> <p>19 fhs@pietragallo.com</p> <p>20 Attorneys for the Defendant,</p> <p>21 Mylan N.V.</p> <p>22</p> <p>23 KIRKLAND & ELLIS, LLP</p> <p>24 BY: BRITTNEY NAGEL, ESQ.</p> <p>25 601 Lexington Avenue</p> <p>New York, New York 10022</p> <p>212-309-4210</p> <p>brittney.nagel@kirkland.com</p> <p>Attorneys for the Defendant,</p> <p>Torrent Pharmaceuticals</p> <p></p> <p>BUCHANAN INGERSOLL & ROONEY, P.C.</p> <p>BY: CHRISTOPHER B. HENRY, ESQ.</p> <p>Carillon Tower</p> <p>227 West Street, Suite 600</p> <p>Charlotte, North Carolina 28202-2601</p> <p>704-444-3475</p> <p>christopher.henry@bipc.com</p> <p>Attorneys for the Defendant,</p> <p>Albertson's LLC</p> <p></p> <p>ALSO PRESENT:</p> <p>Justin Bily - Videographer</p>

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<p style="text-align: right;">Page 341</p> <p>1 I N D E X</p> <p>2</p> <p>3 WITNESS: LAURA PLUNKETT, Ph.D.</p> <p>4</p> <p>5 DIRECT CROSS REDIRECT RECROSS</p> <p>6 MS. MILLER 342</p> <p>7 MR. HARKINS 354</p> <p>8 MS. NAGEL 382</p> <p>9</p> <p>10 E X H I B I T S</p> <p>11 NUMBER DESCRIPTION PAGE</p> <p>12 Exhibit-12 21 CFR 314.420..... 368</p> <p>13</p> <p>14 SPECIAL REQUESTS</p> <p>15 (No special requests)</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p> <p>25</p>	<p style="text-align: right;">Page 343</p> <p>1 de- -- or NDEA, it would be deemed adulterated?</p> <p>2 A. I don't remember the exact question, but</p> <p>3 I certainly do have an opinion. I think it's</p> <p>4 consistent with something that I have stated in my</p> <p>5 report as well.</p> <p>6 Q. And right before I was cut off, I asked</p> <p>7 you who you believed would deem Valsartan</p> <p>8 adulterated, and you said -- and I'm quoting from</p> <p>9 your -- from the transcript -- "I would deem it</p> <p>10 adulterated consistent with the FDA's actions that</p> <p>11 they took and a decision that they made in 2019 when</p> <p>12 they sent the warning letter and made that</p> <p>13 statement." Do you recall that?</p> <p>14 A. Again, not the exact language, but I</p> <p>15 think that's true. I would -- I would stand by that</p> <p>16 testimony, yes.</p> <p>17 Q. So -- so you --</p> <p>18 A. I wouldn't change that.</p> <p>19 Q. So you agree that adulteration is a</p> <p>20 finding that's made by the FDA.</p> <p>21 MR. VAUGHN: Object to form.</p> <p>22 A. In terms of an official regulatory</p> <p>23 finding, yes. The FDA would make that finding;</p> <p>24 however, like in this litigation, or any litigation</p> <p>25 that I've served in, as an expert dealing with</p>
<p style="text-align: right;">Page 342</p> <p>1 THE VIDEOGRAPHER: We are going on the</p> <p>2 record at 9:04 Central Time on February 10th, 2023.</p> <p>3 This is Media Unit No. 1 of the video-recorded</p> <p>4 continuation deposition of Dr. Laura Plunkett</p> <p>5 regarding the Valsartan litigation.</p> <p>6 All counsel will be noted on the</p> <p>7 stenographic record.</p> <p>8 Would the court reporter please swear in</p> <p>9 the witness, and then we can begin.</p> <p>10 L A U R A M. P L U N K E T T, Ph.D., doing</p> <p>11 business at 13923 Carriage Rock Lane, Houston, Texas,</p> <p>12 77336, having been duly sworn by the Notary Public,</p> <p>13 testified as follows:</p> <p>14 MR. VAUGHN: Jessica, before we begin,</p> <p>15 just on the record, we agreed we have a one-hour</p> <p>16 limit between the three Defendants.</p> <p>17 MS. MILLER: Correct.</p> <p>18 MR. VAUGHN: Awesome. Thank you. Go</p> <p>19 ahead.</p> <p>20 CONTINUED REDIRECT EXAMINATION BY MS. MILLER:</p> <p>21 Q. Hi, Dr. Plunkett. Good to see you</p> <p>22 again. I know it's been a while, but do you recall</p> <p>23 saying at your last deposition when you were being</p> <p>24 questioned by Plaintiff's counsel that if at any</p> <p>25 point in time Valsartan contained NDMA, it would be</p>	<p style="text-align: right;">Page 344</p> <p>1 compliance with FDA regulations, it is certainly</p> <p>2 something that I -- I have in the past, and have</p> <p>3 formed an opinion on that, I believe consistent with</p> <p>4 the regulation and consistent with FDA's own finding</p> <p>5 that the product is -- would be deemed adulterated.</p> <p>6 Q. And the FDA made that finding with</p> <p>7 respect to ZHP's API in the warning letter, correct?</p> <p>8 MR. VAUGHN: Object to form.</p> <p>9 A. Yes. I -- well, I don't -- it may be in</p> <p>10 other places, but certainly, it is in the warning</p> <p>11 letter, yes.</p> <p>12 Q. Did you see any other places where the</p> <p>13 FDA made a finding that ZHP's API -- scratch that.</p> <p>14 Did you see any other document in which</p> <p>15 the FDA used the term "adulterated" or "adulteration"</p> <p>16 with respect to ZHP's API?</p> <p>17 MR. VAUGHN: Object to form.</p> <p>18 A. I'd have to go and look to answer that</p> <p>19 fully. I don't recall. It's possible that it is</p> <p>20 discussed on some of the documents on the FDA website</p> <p>21 that are -- that deal with issues related to the</p> <p>22 recall, but I'd have to look. I don't recall.</p> <p>23 Q. Are you aware of any statement the FDA</p> <p>24 said suggesting, or otherwise referencing</p> <p>25 adulteration or adulterated with respect to ZHP's API</p>

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<p style="text-align: right;">Page 345</p> <p>1 prior to the November 2018 warning letter?</p> <p>2 MR. VAUGHN: Object to form.</p> <p>3 A. Based on the evidence I've seen, I can't</p> <p>4 answer that without looking, but I would be surprised</p> <p>5 if they did because, again, when FDA put -- makes</p> <p>6 that determination, it's regulatory finding that</p> <p>7 would trigger a warning letter typically, or some</p> <p>8 official action. Adulteration is one of those</p> <p>9 standards that would be triggered -- one of those</p> <p>10 things that would trigger an actual -- either an</p> <p>11 untitled letter, but most likely a warning letter,</p> <p>12 being issued to the company. So I -- I -- that's</p> <p>13 where I would expect to see it when FDA makes that</p> <p>14 statement.</p> <p>15 Q. Okay. That was a long roundabout</p> <p>16 answer. I just want to make sure I understand. You</p> <p>17 are not aware of the FDA making any finding or</p> <p>18 statement prior to the warning letter of November</p> <p>19 2018 suggesting or stating that ZHP's API was</p> <p>20 adulterated, correct?</p> <p>21 MR. VAUGHN: Object to form.</p> <p>22 A. And I'd answer the same way: I can't</p> <p>23 answer that fully without looking based on the fact</p> <p>24 that you're giving it a specific date; however, as I</p> <p>25 state- -- I -- I tried to point out to you that I</p>	<p style="text-align: right;">Page 347</p> <p>1 failed to comply with CGMP prior to the November 2018</p> <p>2 warning letter, correct?</p> <p>3 MR. VAUGHN: Object to form.</p> <p>4 A. I need to ask you to clarify. Can I ask</p> <p>5 for a clarification of that question? Because I</p> <p>6 think it's a little un- -- it's a little ambiguous.</p> <p>7 Can -- you want me to explain what I'm -- why I'm</p> <p>8 confused?</p> <p>9 Q. Sure.</p> <p>10 A. So are you saying that -- are you</p> <p>11 limiting this to the fact that FDA never made a</p> <p>12 determination that there was a lack of compliance</p> <p>13 with GMP except in a letter that is dated in 2018</p> <p>14 even though it may also reference things that</p> <p>15 happened before 2018, or are you saying that -- are</p> <p>16 you saying that -- are you doing something else? If</p> <p>17 that's what you're answering -- if that's what you're</p> <p>18 asking, I think that's a little more clear, and I can</p> <p>19 answer that question.</p> <p>20 Q. I am asking whether you are aware of any</p> <p>21 statements made by the FDA before the warning letter</p> <p>22 in November 2018 in which the FDA suggested or stated</p> <p>23 that ZHP had failed to comply with CGMP?</p> <p>24 MR. VAUGHN: Object to form.</p> <p>25 Q. It's a very simple question.</p>
<p style="text-align: right;">Page 346</p> <p>1 would expect to find it in official documents, like a</p> <p>2 warning letter, because that is typically where I see</p> <p>3 such statements or decisions discussed.</p> <p>4 Q. Okay. I'm a little confused by your</p> <p>5 answer, because my question was are you aware of, not</p> <p>6 was there. And so I just want to clarify. You are</p> <p>7 not aware of any such finding, statement or</p> <p>8 suggestion prior to November 2018, correct?</p> <p>9 MR. VAUGHN: Object to form.</p> <p>10 A. And I'd answer the same way: I said I</p> <p>11 can't answer that fully without looking, but I was</p> <p>12 trying to explain to you that if -- if it did exist,</p> <p>13 it would be in something like another warning letter.</p> <p>14 I don't recall, and I'd have to go look in the files</p> <p>15 to see if there's anything else.</p> <p>16 Q. Sitting here today, you're not aware of</p> <p>17 such -- of any such statement or suggestion by the</p> <p>18 FDA, correct?</p> <p>19 A. Without --</p> <p>20 MR. VAUGHN: Object to form.</p> <p>21 A. Without looking, that is correct. I'd</p> <p>22 have to go back and look at the documents; that's</p> <p>23 correct.</p> <p>24 Q. And you're also not aware of any</p> <p>25 statement issued by the FDA suggesting that ZHP</p>	<p style="text-align: right;">Page 348</p> <p>1 A. It's really not so simple because they</p> <p>2 can be in a warning letter where they made a</p> <p>3 statement re: referencing actions or activities that</p> <p>4 predate --</p> <p>5 Q. I didn't ask that.</p> <p>6 A. -- a statement, but certainly --</p> <p>7 Q. I'm asking about the date of a</p> <p>8 statement. Are you aware of any statement made by</p> <p>9 FDA before November 2018? That's the question I'm</p> <p>10 asking. You can answer --</p> <p>11 MR. VAUGHN: Object to form.</p> <p>12 Q. -- another question to Brett.</p> <p>13 MR. VAUGHN: Argumentative.</p> <p>14 Q. My question is, are you aware of a</p> <p>15 statement made by FDA before November 2018 in which</p> <p>16 FDA suggested or stated that ZHP had been in</p> <p>17 violation of CGMP?</p> <p>18 MR. VAUGHN: Object to form.</p> <p>19 Argumentative. Asked and answered.</p> <p>20 A. So I -- I can't answer that question</p> <p>21 without looking as well, because now I'm -- I'm</p> <p>22 thinking as I listen to your question, are you only</p> <p>23 limiting it to Valsartan and that API? Then that's a</p> <p>24 little easier question to answer.</p> <p>25 Again, there's -- there's multiple times</p>

<p style="text-align: right;">Page 349</p> <p>1 that FDA has interacted with the -- ZHP, but if</p> <p>2 you're talking about specific to the issue of</p> <p>3 Valsartan and the CGMPs for Valsartan, is that what</p> <p>4 you're asking?</p> <p>5 Q. That is what I'm asking.</p> <p>6 A. I'd have to go look. I can't answer</p> <p>7 that to say for sure, but certainly, they did do that</p> <p>8 in 2018; that is correct.</p> <p>9 Q. Sitting here today, can you point to any</p> <p>10 statement or suggestion made by the FDA before</p> <p>11 November 2018 regarding ZHP's compliance with CGMP</p> <p>12 with respect to Valsartan?</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 A. So I'd answer the same way: I'd have to</p> <p>15 go look. I can't answer that without looking to see</p> <p>16 if there is another document, but certainly, they do</p> <p>17 do that in the 2018 document.</p> <p>18 Q. But you can't point right now without</p> <p>19 looking to any other document. Is that correct?</p> <p>20 MR. VAUGHN: Object to form.</p> <p>21 Argumentative.</p> <p>22 A. Not without looking, I -- I cannot name</p> <p>23 you another document; that is true. But again, I --</p> <p>24 I can't say that there is not such a document.</p> <p>25 Q. Do you ever recall seeing such a</p>	<p style="text-align: right;">Page 351</p> <p>1 Q. Are you or are you --</p> <p>2 A. How important the CGMP standard is to</p> <p>3 that.</p> <p>4 Q. Are you or are you not offering an</p> <p>5 opinion about ZHP's compliance with CGMP?</p> <p>6 A. From the aspect as stated in my report,</p> <p>7 I am giving you an opinion as it relates to the issue</p> <p>8 of how CGMP ties to the adulteration standard, yes,</p> <p>9 but I did not do the full analysis on my own of all</p> <p>10 of the documents related to the GMP issues. Again,</p> <p>11 that's in the scope of Dr. Bain, so I'd suggest that</p> <p>12 that's where you would go to ask a lot of the</p> <p>13 questions you may have about the documents in that</p> <p>14 area.</p> <p>15 Q. So you're offering an opinion about</p> <p>16 CGMP, but you don't know whether FDA ever addressed</p> <p>17 ZHP's compliance with CGMP with respect to Valsartan</p> <p>18 before the November 2018 warning letter.</p> <p>19 MR. VAUGHN: Object to form. Compound.</p> <p>20 Argumentative.</p> <p>21 A. So I'm saying I'd have to go back and</p> <p>22 look at the documents. I don't recall. That's all</p> <p>23 I'm stating for you. Because in my report, if you</p> <p>24 look at what I address as it relates to the</p> <p>25 statement, I point to the 2018 letter.</p>
<p style="text-align: right;">Page 350</p> <p>1 document?</p> <p>2 MR. VAUGHN: Object to form.</p> <p>3 A. I have -- I don't recall ever asking the</p> <p>4 question of the doc- -- I don't recall ever assessing</p> <p>5 the documents the way you're asking the question, so</p> <p>6 that's why I'm -- I'm -- I'm stating it the way I am.</p> <p>7 It's not that I went about review of the documents to</p> <p>8 look for a statement specific -- as specific as you</p> <p>9 are asking it.</p> <p>10 I'm not the -- I'm not the only one</p> <p>11 dealing with the issues related to GMP, so it's very</p> <p>12 possible there are other letters that are in the</p> <p>13 documents that I've looked at that I just don't</p> <p>14 remember, because they're not ones that I state to --</p> <p>15 I don't cite to in my report, for example, in terms</p> <p>16 of the description of my opinion.</p> <p>17 Q. Do you consider yourself to be offering</p> <p>18 a CGMP opinion in this litigation?</p> <p>19 A. I'm not the CGMP expert in terms of all</p> <p>20 of the details of the CGMP inspections compliance,</p> <p>21 that is, I believe, Dr. Bain in the litigation, but I</p> <p>22 certainly have expertise around the issues of the</p> <p>23 importance of CGMP as described in my report to</p> <p>24 complying fully and as it relates to the issue of</p> <p>25 adulteration.</p>	<p style="text-align: right;">Page 352</p> <p>1 Q. Do you point to anything else?</p> <p>2 A. In my report as stated, no. But what</p> <p>3 I'm telling you, I did have access to a variety of</p> <p>4 other documents. And as you're asking the question,</p> <p>5 I'd have to go back and look to see whether or not</p> <p>6 any of the other documents that I have seen or that</p> <p>7 have been attached as exhibits to depositions that I</p> <p>8 have reviewed indeed address your point.</p> <p>9 Q. If the FDA had addressed adulteration or</p> <p>10 CGMP violations with respect to Valsartan before</p> <p>11 November '18, wouldn't you have included that in your</p> <p>12 report?</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 A. It depends.</p> <p>15 Q. What does it depends on?</p> <p>16 A. It depends upon the -- how the evidence</p> <p>17 related in terms of the opinions -- the -- the way</p> <p>18 that -- the information I've reviewed, the opinions</p> <p>19 that I've expressed. I don't recall that document,</p> <p>20 but as I always do in my deposition, if you have one,</p> <p>21 show it to me. I don't recall it, but I can't say</p> <p>22 for sure that I have ruled out that there's nothing</p> <p>23 there because that was beyond the scope of what I</p> <p>24 did. Looking for and reviewing and having at the tip</p> <p>25 of my memory everything that I -- that I have</p>

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<p style="text-align: right;">Page 353</p> <p>1 reviewed, there are other documents there. They 2 looked and did other GMP inspections in the past. 3 Where the GM- -- where the Valsartan line was, 4 indeed, operating at ZHP. I don't recall a document, 5 that's what I think I've told you already. But I 6 can't -- in order to fully answer and say absolutely, 7 there is no such document, I'd have to go look. 8 I don't know how else to -- to answer 9 the question for you in order to be accurate in terms 10 of what my memory is and what the -- the breadth of 11 the information that is available to me. 12 Q. Are you offering an opinion on whether 13 the FDA made any statements regarding adulteration or 14 CGMP violations with respect to ZHP's Valsartan API 15 before November 2018? 16 A. About their statement? No. Because 17 I -- that is not in my report. What I cite to in my 18 report is the 2018 statement. 19 Q. So you do not have an opinion as to 20 whether or not that was the first time the FDA 21 offered a statement or suggestion regarding 22 adulteration or CGMP with respect to API -- ZHP? You 23 don't have -- 24 MR. VAUGHN: Object to form. 25 A. I have not formed that opinion as you're</p>	<p style="text-align: right;">Page 355</p> <p>1 Ms. Miller, correct? 2 A. Yes. 3 Q. You're aware that the FDA has never sent 4 a warning letter to Teva related to their Valsartan 5 finished-dose drug product. 6 A. So I can't verify that by the research 7 that I have done. In other words, I haven't looked 8 at all of the warning letters that have come in, for 9 example, what might have happened after the warning 10 letter from 2018, but I can't -- I certainly have not 11 referred to one, and I have not formed an opinion 12 about any warning letters to Teva after 2018 'cause I 13 don't cite to them in my report. Does that answer 14 your question? 15 Q. You're -- you're not aware of any 16 warning letter like the one that was sent to ZHP that 17 was sent to Teva related to their finished-dose 18 Valsartan drug product. Is that correct? 19 A. I have not seen such a warning letter; 20 that is true. 21 Q. Are you aware of any public statement by 22 FDA or finding related to Teva's finished-dose drug 23 product being adulterated? 24 MR. VAUGHN: Object to form. 25 A. Are you being broad as far as public</p>
<p style="text-align: right;">Page 354</p> <p>1 asking it, no. And in order to verify one way or the 2 other for you, I'd have to go and look. 3 Q. And you don't recall that. Sitting here 4 today, you don't recall whether that's the first time 5 or not. 6 MR. VAUGHN: Object to form. 7 A. I can't tell you without looking 8 accurately, whether that is, indeed, the first time. 9 I -- I certainly am aware that -- that that is a time 10 that's highly relevant in this case, and I have 11 discussed it and described it in my report. 12 MS. MILLER: Steve, she's all yours. 13 RE-CROSS-EXAMINATION BY MR. HARKINS: 14 Q. Good morning, Dr. Plunkett. How are you 15 doing? 16 A. Fine. Thank you. 17 Q. I would like to follow up on a few 18 things from the end of your deposition. 19 As a reminder in case you've forgotten, 20 I represent the Teva Defendants, one of the 21 finished-dose manufacturers in this case. You're 22 aware of that, right? 23 A. Yes. 24 Q. You just testified a little bit about 25 the warning letter that was directed to ZHP with</p>	<p style="text-align: right;">Page 356</p> <p>1 statements? And the reason I ask that is so, for 2 example, at the FDA website where they discuss the 3 recall, they're listed as a product that's been 4 recalled, and it's listed as being recalled because 5 of the presence of the NDMA. And we know that the 6 presence of the NDMA is what triggered the 7 adulteration finding by the government, by -- by FDA, 8 so that evidence exists. But maybe you're meaning 9 something more specific, so.... 10 Q. I -- I -- I think I am. Let me try and 11 help. 12 I understand your opinion with regard to 13 adulteration. I am asking if you are aware -- and I 14 am being broader than just a warning letter -- of any 15 public statement by the FDA specifically that Teva's 16 finished-dose drug product was adulterated. 17 MR. VAUGHN: Object to form. 18 A. Okay. So do you -- you -- are you 19 asking me do they use the -- a specific set of words 20 or.... because I do think in the -- I'd have to go 21 pull them. I have some of them printed out here like 22 I had at the first deposition. I'd have to go back 23 and look at the statements from the FDA website over 24 time because they mention API from Teva, from 25 Torrent. From a variety of different manufacturers.</p>

<p style="text-align: right;">Page 357</p> <p>1 Not API --</p> <p>2 Q. I am being --</p> <p>3 A. -- finished dose. Finished-dose</p> <p>4 product.</p> <p>5 Q. I am being specific to Teva's</p> <p>6 finished-dose drug product and the actual term</p> <p>7 "adulteration" as set forth in the Food, Drug and</p> <p>8 Cosmetics Act, if you are aware of any public</p> <p>9 statement, including on those statements that you are</p> <p>10 referencing, declaring that Teva's finished-dose</p> <p>11 Valsartan drug product was adulterated.</p> <p>12 A. I'd have to go look to see the exact</p> <p>13 terms they use, but I would argue -- not argue. I</p> <p>14 would point out to you that the fact that the product</p> <p>15 was "recall" was evidence of, and linkage to that</p> <p>16 finding of adulteration. That's what led to the</p> <p>17 recall. And their product, indeed, is stated in the</p> <p>18 doc- -- in different public documents to have been</p> <p>19 subject to the recall.</p> <p>20 But if you are looking for a specific</p> <p>21 sentence that says FDA sent a warning letter saying</p> <p>22 that Teva had an adulterated product or FDA found</p> <p>23 Teva's product to be adulterated, those specific</p> <p>24 words, I'd have to go and look. I don't know. But</p> <p>25 basically, to me, as a regulatory expert, the issue</p>	<p style="text-align: right;">Page 359</p> <p>1 finished-dose product was adulterated?</p> <p>2 MR. VAUGHN: Object to form.</p> <p>3 A. And I'd have to answer it the exact same</p> <p>4 way: The way you're asking -- if -- if you're asking</p> <p>5 me that specific phrase, I'd have to go and look in</p> <p>6 the public statements, but how -- what I'm pointing</p> <p>7 out to you is regardless of whether those specific</p> <p>8 words are there is -- the product is what it is.</p> <p>9 It's an adulterated product that was included in the</p> <p>10 recall.</p> <p>11 Q. And Dr. Plunkett, I am not asking you to</p> <p>12 speculate on documents that you haven't seen.</p> <p>13 Without going and reviewing additional documents, as</p> <p>14 you sit here today, you are not aware of that</p> <p>15 specific statement with respect to Teva's Valsartan</p> <p>16 finished-dose drug product, correct?</p> <p>17 MR. VAUGHN: Object to form.</p> <p>18 A. I am not aware of those specific words;</p> <p>19 that is correct. But again, I think that there's</p> <p>20 context here that is important to understand, and</p> <p>21 that's all I'm trying to point out to you. Is that</p> <p>22 the con- -- the -- the use of those words is -- is --</p> <p>23 is one thing, but there's also the understanding of</p> <p>24 what the recall was based on, which we know there are</p> <p>25 many -- there's a variety of public statements from</p>
<p style="text-align: right;">Page 358</p> <p>1 is they were recalled. It is stated they were part</p> <p>2 of the recall, and -- and the evidence shows and the</p> <p>3 facts of the case show, that that recall was linked</p> <p>4 to the finding of adulteration in the API.</p> <p>5 Q. Dr. Plunkett, you're not aware, as you</p> <p>6 sit here today, without reviewing additional</p> <p>7 material, of any such statement. Is that fair?</p> <p>8 MR. VAUGHN: Object to form.</p> <p>9 A. I'm not aware of those specific words as</p> <p>10 you're asking, but I'm trying to point out to you</p> <p>11 that regardless of whether those words are used, the</p> <p>12 fact that the public documents describe Teva's</p> <p>13 product as part of the recall, that there is</p> <p>14 essentially linking those to the issue of</p> <p>15 adulteration. That was the reason for the recall, so</p> <p>16 I don't think you can walk away from that. Their</p> <p>17 product would be -- because of the recall, their</p> <p>18 product is also adulterated because of the fact that</p> <p>19 it contains the -- the ZHP API.</p> <p>20 Q. Dr. Plunkett, I'm not asking or -- or --</p> <p>21 or requesting that you change your opinion that I</p> <p>22 understand as to whether you believe the product was</p> <p>23 adulterated; I'm just trying to confirm, are you</p> <p>24 aware, as you sit here today, of any public statement</p> <p>25 that specifically indicates Teva's Valsartan</p>	<p style="text-align: right;">Page 360</p> <p>1 Teva themselves about them recalling their product.</p> <p>2 Q. Understood. Dr. Plunkett, is, in your</p> <p>3 opinion, that every product that is recalled is</p> <p>4 adulterated under the FD&C Act?</p> <p>5 A. No. There's different reasons for</p> <p>6 recall, if that's what you're asking me.</p> <p>7 Adulteration -- adulterated products are often</p> <p>8 subject to recall, but there's -- you know, I -- I</p> <p>9 wouldn't say it's at 100 percent all the time that</p> <p>10 they would be recalled. It would depend whether</p> <p>11 there's anything to recall, No. 1. And then there's</p> <p>12 other reasons to recall besides adulteration.</p> <p>13 Misbranding, for example, is a reason to</p> <p>14 potentially recall if the FDA makes the decision that</p> <p>15 the issues related to the misbranding are serious</p> <p>16 enough to raise a safety concern for the public.</p> <p>17 Illegally -- illegally selling a product</p> <p>18 that is a -- another example would be illegally</p> <p>19 selling a product that is making drug claims, which</p> <p>20 isn't regulated as a drug could be subject to a</p> <p>21 potential recall as well. There's a variety of</p> <p>22 different ways.</p> <p>23 Q. And just to confirm, there -- there are</p> <p>24 other different ways. Those aren't specifically the</p> <p>25 things that are at issue in this case, correct?</p>

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<p style="text-align: right;">Page 361</p> <p>1 MR. VAUGHN: Object to form.</p> <p>2 A. That is -- based on the recall that is</p> <p>3 at issue in this case; that is true. It is around an</p> <p>4 adulteration issue.</p> <p>5 Q. Now, in -- in addition to issuing a</p> <p>6 warning letter, the FDA has any number of other</p> <p>7 enforcement mechanisms that it can take when it deems</p> <p>8 a product to be adulterated or otherwise</p> <p>9 inappropriately present on the market. Is the right?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. If you're asking me generally about</p> <p>12 their --</p> <p>13 Q. Generally, yeah.</p> <p>14 A. -- mobilities, yes. Generally they have</p> <p>15 a variety of enforceabilities; that is true.</p> <p>16 Q. They could seize adulterated product in</p> <p>17 coordination with DOJ. Is that right?</p> <p>18 A. If it got raised to that level, yes. It</p> <p>19 typically doesn't happen unless the company refuses</p> <p>20 first to cooperate.</p> <p>21 Q. They can issue consent decrees. They</p> <p>22 can do import alerts. Those type of things?</p> <p>23 A. Import alerts, absolutely. Those are a</p> <p>24 very -- that happens all the time. That's actually a</p> <p>25 pretty easy thing to do. But the -- the issues</p>	<p style="text-align: right;">Page 363</p> <p>1 Q. Yes.</p> <p>2 A. Yeah, that's correct. It can be a</p> <p>3 voluntary. And -- and typically, most recalls are</p> <p>4 voluntary, again, because most companies will</p> <p>5 cooperate when an issue is identified and brought to</p> <p>6 their attention.</p> <p>7 Q. And as we know from this case, they can</p> <p>8 send a warning letter to a company, right?</p> <p>9 MR. VAUGHN: Object to form. Vague. As</p> <p>10 too vague.</p> <p>11 A. Well, it depends.</p> <p>12 Q. Sorry. If the FDA sends a warning</p> <p>13 letter. Let me correct the question, Dr. Plunkett.</p> <p>14 MR. VAUGHN: I was trying to help.</p> <p>15 Q. If FDA --</p> <p>16 MR. HARKINS: Sorry. I understood the</p> <p>17 objection. Withdrawn.</p> <p>18 Q. FDA can obviously send a warning letter</p> <p>19 to a company, correct?</p> <p>20 A. A company that it regulates as it</p> <p>21 relates to a product; yes, that's correct. If it --</p> <p>22 if it has -- if FDA is -- if a company has a product</p> <p>23 under the purview of FDA, yes, FDA can send a warning</p> <p>24 letter.</p> <p>25 Q. And as you sit here today, you're not</p>
<p style="text-align: right;">Page 362</p> <p>1 related to seizures, those kinds of things, those are</p> <p>2 things that typically don't happen unless there's</p> <p>3 been some -- in my experience, there's been some lack</p> <p>4 of cooperation for the -- on a -- by a company to</p> <p>5 cooperate in terms of taking care of the issue.</p> <p>6 Q. And they can take a number of actions</p> <p>7 after an FDA inspection. They could take a --</p> <p>8 something like an Official Action Indicated if they</p> <p>9 find problems at the facility?</p> <p>10 MR. VAUGHN: Object to form.</p> <p>11 A. Are you asking is that possible for FDA</p> <p>12 to do? If that's what you're asking, yes, that --</p> <p>13 there are different things that FDA can do.</p> <p>14 Q. Yes, no. That's -- that's what I'm</p> <p>15 asking generally. They could also take a Voluntary</p> <p>16 Action Indicated after inspection of a facility as</p> <p>17 well generally.</p> <p>18 MR. VAUGHN: Object to form.</p> <p>19 A. By "they" do you mean the company, or by</p> <p>20 "they" do you mean --</p> <p>21 Q. I mean FDA.</p> <p>22 A. Oh, FDA. They can ask for vol- -- oh,</p> <p>23 sure. They can ask a company or they can inquire or</p> <p>24 write to a company and ask for voluntary action. Is</p> <p>25 that what you're asking?</p>	<p style="text-align: right;">Page 364</p> <p>1 aware of FDA taking a single one of these enforcement</p> <p>2 steps with respect to Teva and their Valsartan</p> <p>3 finished-dose drug product, are you?</p> <p>4 MR. VAUGHN: Object to form.</p> <p>5 A. Well, certainly, recall they did. Is</p> <p>6 that what you're asking me? There was a recall that</p> <p>7 was asked for. But are you asking me about seizures</p> <p>8 and junctions, import alerts? What are you asking?</p> <p>9 Q. Other than the voluntary recall that</p> <p>10 Teva initiated in coordination with FDA, are you</p> <p>11 aware of any other official action like any of those</p> <p>12 we just described taken by FDA with respect to Teva's</p> <p>13 Valsartan finished-dose drug product?</p> <p>14 MR. VAUGHN: Object to form.</p> <p>15 A. I -- off the top of my head, I am not</p> <p>16 aware -- or I couldn't name one for you. But again,</p> <p>17 I can't -- I can't -- I can't with 100 percent surety</p> <p>18 say that such doesn't exist somewhere. I just -- I'm</p> <p>19 not aware of it. That's the best way I can answer it</p> <p>20 for you.</p> <p>21 Q. Understood. At the end of your</p> <p>22 deposition last time, you discussed the finished-drug</p> <p>23 manufacturer obtaining access to the closed portion</p> <p>24 of the DMF for API referenced in its ANDA. Do you</p> <p>25 recall that testimony?</p>

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<p style="text-align: right;">Page 365</p> <p>1 A. In general terms we did; yes, that's 2 correct. 3 Q. You cannot identify any section of the 4 Code of Federal Regulations that requires a 5 finished-dose manufacturer to obtain access to the 6 DMF for API referenced in its ANDA? 7 MR. VAUGHN: Object to form. 8 A. Off the -- no. But again, the -- the 9 FDA regulations as they exist are a -- a floor, a 10 ceiling, a minimum set. I am aware of the fact 11 'cause I've worked with companies before that go to 12 someone when they're going to be considering them as 13 a supplier and asking for an NDA or a confidentiality 14 agreement to review in detail files that relate to a 15 process, so it can be done. 16 Q. Again, I -- 17 A. But that -- but I would agree with you. 18 I don't -- I don't believe there -- any of the 19 regulations address that specifically. 20 Q. And similarly, you cannot identify any 21 CGMP that requires a finished-dose manufacturer to 22 obtain access to the DMF for API referenced in its 23 ANDA, correct? 24 MR. VAUGHN: Object to form. 25 A. Well, the CGMP regulations are more</p>	<p style="text-align: right;">Page 367</p> <p>1 A. Yes. I answered that, and I said yes, 2 that I -- I am not aware of that. And the reason is, 3 first off, the regulations are not that prescriptive; 4 however, there is guidance around this issue and the 5 guidance that FDA has -- has produced indicates that. 6 That's what I'm referring to, is the idea that 7 there's an expectation, and actually a -- the -- the 8 regulations broadly require that a finished-dose 9 manufacturer take all steps necessary to ensure that 10 the product they're selling is consistent and in 11 compliance with CGMP. 12 Q. Dr. Plunkett, I'm gonna go ahead and 13 just Screen Share a section of the CFR here. We can 14 introduce this as an exhibit as well. Are you 15 familiar with this regulation? 16 A. Yes. If you want to talk about a 17 specific section, I'll -- I'll -- we'll need to 18 review it. 19 Q. Understood. And this is cited in your 20 Reliance list. I think generally under 21 CFR DMF. 21 Is -- is this what you're referring to there? 22 A. Yes. This is part of it. This is just 23 one page of it. But yes, that's correct. 24 Q. Understood. And I'm happy to upload 25 this and let you have any time to review it if you</p>
<p style="text-align: right;">Page 366</p> <p>1 broad than that. That would be a pretty prescriptive 2 step to be asking that someone to do -- or asking to 3 be in the regulations, but I would argue that -- or 4 not -- I don't want to argue. I would point out that 5 the CGMP regulations require that a finished-dose 6 manufacturer have processes in place, a good quality 7 system, management system in place to ensure that 8 their product is being manufactured and produced 9 consistent with GMPs. That's part of that as we 10 talked about in some detail, I believe. I don't 11 think it may have been with you. It may have been 12 with Ms. Miller back -- back in January on the first 13 day. 14 Those quality system requirements or 15 those quality systems include the -- the fact that 16 the finished-dose manufacturer has to have 17 appropriate processes in place to ensure that their 18 drug, indeed, is being produced consistent with GMP. 19 Q. And -- and I think you may have answered 20 my question at the beginning, but just to confirm. I 21 am not asking about broader quality system issues; I 22 am just trying to confirm that there is no specific 23 prescription under CGMPs requiring a finished-drug 24 manufacturer to obtain access to the DMF in order to 25 reference API in its ANDA, correct?</p>	<p style="text-align: right;">Page 368</p> <p>1 need, but looking just down under the first part here 2 on subsection A. Do you see that? 3 A. I see section -- yes. I see that 4 section, yes. 5 MR. VAUGHN: Steve, do you mind 6 uploading it just so I can review the full document 7 as well. 8 MR. HARKINS: Yeah. And this has been 9 into the -- popped in the Dropbox. 10 Is the videographer on to add this to an 11 exhibit? I think we're on the Novak Trial Services 12 platform today. 13 MR. VAUGHN: That's the one I'm on. 14 THE VIDEOGRAPHER: Yes. It -- it should 15 be in there now. 16 MR. HARKINS: I'm up- -- re-uploading it 17 now. Give me one second. 18 (Exhibit-12, 21 CFR 314.420, marked for 19 identification.) 20 THE WITNESS: Can I ask a question? 21 This will be Exhibit -- a new exhibit that -- you're 22 gonna make this Exhibit-12. Is that correct? 23 MR. HARKINS: Yes. It will be a new 24 exhibit. 25 THE WITNESS: Okay.</p>

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<p style="text-align: right;">Page 369</p> <p>1 MR. HARKINS: And do you have access to</p> <p>2 the Dropbox, Dr. Plunkett?</p> <p>3 THE WITNESS: I -- well, I don't think I</p> <p>4 need it for this document. It's two pages. I'm</p> <p>5 generally familiar with what's here. Ask your</p> <p>6 question. I may need you to go to page 2. But if</p> <p>7 you're on Part A, I can see it, so go ahead -- right</p> <p>8 ahead and ask your question.</p> <p>9 MR. VAUGHN: I'm good to go, Steve. And</p> <p>10 I've got it pulled up now.</p> <p>11 MR. HARKINS: Great.</p> <p>12 Q. All right. And Dr. Plunkett, if you</p> <p>13 need any time or questions about the document, just</p> <p>14 let me know.</p> <p>15 Looking under subpart A, and I'm asking</p> <p>16 to start with the -- it is the phrase after the colon</p> <p>17 "purposes." If you're able to see it here.</p> <p>18 A. Yes, I see it. "To permit the holder."</p> <p>19 Q. And go ahead and just read that sentence</p> <p>20 into the record.</p> <p>21 A. "To permit the holder to incorporate the</p> <p>22 information by reference when the holder submits an</p> <p>23 investigational new drug application under part 312</p> <p>24 or submits an application or an abbreviated</p> <p>25 application or an amendment or supplement to them</p>	<p style="text-align: right;">Page 371</p> <p>1 other person to be, yes.</p> <p>2 Q. And understanding it might be broader,</p> <p>3 but in this case, for example, that would be Teva and</p> <p>4 Torrent as the finished-dose manufacturers</p> <p>5 referencing ZHP's Valsartan API DMF. Is that right?</p> <p>6 A. Yes. But I'm a -- I'm aware of the</p> <p>7 fact that they did; that is correct. And that --</p> <p>8 that relationship is true based upon the way you've</p> <p>9 described it.</p> <p>10 Q. And just to return to one of your</p> <p>11 statements about the regulation, are you aware of any</p> <p>12 FDA guidance, and again, that requires a</p> <p>13 finished-dose manufacturer to obtain access to the</p> <p>14 DMF for API referenced in its ANDA?</p> <p>15 MR. VAUGHN: Object to form.</p> <p>16 A. State the first part of your sentence</p> <p>17 again?</p> <p>18 Q. I -- I believe you've indicated --</p> <p>19 'cause I had asked some questions about whether there</p> <p>20 was anything in the CFR or in GMPs as to whether</p> <p>21 there was anything that specifically required a</p> <p>22 finished-dose manufacturer to either seek or obtain</p> <p>23 access to API -- sorry -- to the DMF for its API. My</p> <p>24 question is, can you identify any FDA guidance that</p> <p>25 requires a finished-dose manufacturer to obtain</p>
<p style="text-align: right;">Page 370</p> <p>1 under this part, or to permit the holder to authorize</p> <p>2 other persons to rely on the information to support a</p> <p>3 submission to FDA without the holder having to</p> <p>4 disclose the information to the person."</p> <p>5 Q. And -- and I'm happy to -- if you want</p> <p>6 to qualify this: Generally speaking, this is the</p> <p>7 description in the CFR of the purpose of Drug Master</p> <p>8 Files?</p> <p>9 A. Yes, that's correct.</p> <p>10 Q. And in that language that you just read,</p> <p>11 the holder in this case would be the DMF holder or</p> <p>12 the API manufacturer. Is that correct?</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 A. It would be -- this is the DMF holder,</p> <p>15 and obviously the DMF holder could be more than an</p> <p>16 API manufacturer. But yes, an API manufacturer in</p> <p>17 this case was the Drug Master File holder; that is</p> <p>18 true.</p> <p>19 Q. And when it says "other persons to rely</p> <p>20 on the information," those other persons would be</p> <p>21 finished-dose manufacturers from, for example,</p> <p>22 another company, correct?</p> <p>23 MR. VAUGHN: Object to form.</p> <p>24 A. Well, I think they're pretty broad, but</p> <p>25 that generally would be who I would be expecting that</p>	<p style="text-align: right;">Page 372</p> <p>1 access to the DMF for API referenced in its ANDA?</p> <p>2 A. So I think -- I -- I think you're asking</p> <p>3 something other than the way I'm hearing it, 'cause I</p> <p>4 would say to you, this regulation specifically is</p> <p>5 requiring them to reference it obviously. If they're</p> <p>6 going -- if they're gonna be permitted to -- if</p> <p>7 they're -- if they're gonna be permitted to reference</p> <p>8 it, this is the way they would do it, I guess is what</p> <p>9 I'm saying, but I think you're asking something else.</p> <p>10 I -- I think what you're -- maybe I'm</p> <p>11 wrong, but I think where you're going -- maybe you</p> <p>12 need to reask the question 'cause I'm not really sure</p> <p>13 what you're trying to ask in terms of the -- because</p> <p>14 this particular -- this particular part of the</p> <p>15 language would, indeed, state what the holder should</p> <p>16 be doing in terms of referencing the DMF.</p> <p>17 Q. And -- and just to be clear -- and maybe</p> <p>18 this is two questions. First, Dr. Plunkett, this</p> <p>19 regulation does not require an ANDA applicant to</p> <p>20 obtain access to the closed portion of the DMF,</p> <p>21 correct?</p> <p>22 A. Oh. That's a different -- okay. I</p> <p>23 didn't hear "closed portion" in your other question.</p> <p>24 That's why I was confused.</p> <p>25 Okay. So yes; that is correct. It does</p>

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<p style="text-align: right;">Page 373</p> <p>1 not require them to access the closed portion; that 2 is true. This is not there. 3 Q. And -- 4 A. But again, there's other -- there's 5 other regulations or other guidance that I was 6 talking about when I was referencing that issue. 7 Q. And that is my question. Are you aware 8 of any guidance from FDA that requires an ANDA 9 applicant to obtain access to the closed portion of a 10 DMF? 11 MR. VAUGHN: Object to form. 12 A. I think I answered that for you earlier. 13 I said I don't recall -- I don't -- I don't think 14 there's a specific language to the regulation to 15 require it in the way you're stating it; however, 16 they do require compliance of GMPs. And if the only 17 way to ensure compliance, in my view, for example, in 18 this case, is to understand the details on whether or 19 not the company making the API has -- is complying 20 with those GMPs having done the full risk assessment 21 and all those things, I don't know how you do that 22 without getting into some of the closed portion of 23 the -- of the Drug Master File. 24 But I -- that's -- that's -- I don't 25 think that's what you're asking me, so I tried to</p>	<p style="text-align: right;">Page 375</p> <p>1 report, is the regulations for the finished-dose 2 manufacturer that are applicable which would require 3 them to take the steps they need to take to ensure 4 that their product is being manufactured consistent 5 with GMPs which, in my view, could include access to 6 the closed portion. And in my experience working 7 with companies, that's what companies have done. 8 Q. So I just want to clarify. Is it your 9 opinion that any finished-dose manufacturer who does 10 not obtain access to the closed portion of the DMF 11 violation of CGMPs? 12 A. No. I'm not implying that. That's a 13 broader statement than I think I -- I have stated. 14 Do you want me to explain? 15 Q. Maybe I can clarify. I understand it is 16 your opinion in this case that the finished-dose 17 manufacturers should have done that. Is it your 18 opinion that any finished-dose manufacturer who does 19 not also manufacture the API needs to obtain access 20 to the closed portion of the DMF in order to comply 21 with CGMP? 22 MR. VAUGHN: Object to form. 23 A. I think that is not an opinion -- 24 opinion that I have formed at this time, no. 25 However, I would couch that by saying that it's</p>
<p style="text-align: right;">Page 374</p> <p>1 answer it first. I don't believe there's specific 2 language the way you are stating it, but that doesn't 3 mean the finished-dose manufacturer doesn't have an 4 obligation under the law, the regulations and also as 5 set forth in the guidance to take steps to ensure 6 that their drug that they're selling, their finished 7 dose is, indeed, in compliance with GMP. 8 Q. Well, maybe -- let me try and break that 9 down a little bit. 10 You don't cite to any document in your 11 report which identifies a requirement for a 12 finished-dose drug manufacturer to obtain access to 13 the closed portion of a DMF, do you? 14 A. I don't state an -- an opinion that way. 15 No, I don't. If that's what you're asking me. I 16 don't have a statement that proactively states 17 exactly what you did; however, I have opinions that 18 are relevant to answering that question. 19 Q. Understood. And I just want to be 20 clear. You don't identify any document on your 21 Reliance list which requires a finished-dose 22 manufacturer to obtain access to the closed portion 23 of a DMF, do you? 24 A. There's not, no. But again, it -- 25 what -- what is the step there, as I discuss in my</p>	<p style="text-align: right;">Page 376</p> <p>1 probably most important. I might have that -- that 2 opinion if you added the clause, in cases where the 3 API manufacturer is using a process that is -- that 4 is different than the process that was part of the 5 listing of the monograph for the referenced listed 6 drug. 7 Q. Okay. So with that qualification, then, 8 is it your opinion that any finished-dose 9 manufacturer who does not obtain access to the DMF 10 violation of CGMP or that DMF, does not use the same 11 manufacturing process as the referenced listed drug? 12 MR. VAUGHN: Object the form. 13 A. I would -- I would -- I would say that 14 that -- it -- that could be an issue, yes; that's 15 correct. I mean, I think I would couch that with, it 16 could. Because I -- it would really depend on the 17 circumstances and the conditions. 18 Certainly, the regulations do not put 19 out the requirement the way -- I think I've agreed 20 with you on that. I -- the regulations don't make it 21 an absolute requirement for the company to take that 22 step, but as I've tried to explain, that the issue in 23 this case is different. The issue in this case -- 24 and I -- I think I have formed the opinion, and I 25 don't want to go back over that again, but</p>

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<p style="text-align: right;">Page 377</p> <p>1 essentially you know what my opinion is. I do 2 believe, in this case, they should have done that. 3 Q. And I'm gonna go ahead and take that 4 down. And if for any reason you need to see that 5 again, Dr. Plunkett, let me know. 6 Dr. Plunkett, at the end of your 7 deposition last time, you also testified that the 8 finished-dose manufacturers, including Teva, should 9 have done what Novartis did to identify the NDMA 10 impurity. Do you recall that testimony? 11 A. I don't know exactly how I stated it, 12 but I certainly do -- do believe that -- that as -- 13 as -- I think what I stated was we know that a 14 finished-dose manufacturer did do it, so it could 15 have been done. And certainly, that would have been 16 something that would have made sense for these 17 companies to do. They didn't do it. But certainly, 18 they could have, and I believe they should have. 19 Q. Have you reviewed documents to determine 20 how Novartis identified, and then structurally 21 characterized, the NDMA in Valsartan API? 22 MR. VAUGHN: Object to form. 23 Foundation. 24 A. I have re- -- I have reviewed deposition 25 testimony that talks about some of the internal</p>	<p style="text-align: right;">Page 379</p> <p>1 A. I can't answer that either without 2 looking. I don't know. I don't know whether that's 3 addressed in the documents I have seen. 4 Q. And sitting here, you don't know either 5 way, do you? 6 A. Without -- 7 MR. VAUGHN: Object to form. 8 A. Without looking at the documents that I 9 know describe it, I don't recall that discussion of 10 why it was done. It's my understanding they were 11 looking for new -- here's what I do know. I -- it 12 was my understanding that Novartis was looking to 13 qualify as a new supplier. I don't know for what 14 purpose generally. I don't know whether, you know, 15 they had an ANDA at issue. I don't know those 16 details because I don't have a lot of discovery 17 documents from Novartis that describes their 18 motivation. 19 Q. And again, one way or another, do you 20 know whether Novartis identified, and then 21 structurally characterized, NDMA using a theoretical 22 analysis of the route of synthesis? 23 MR. VAUGHN: Object to form. 24 A. So that's beyond the scope of what I 25 looked at, although I do believe that that is</p>
<p style="text-align: right;">Page 378</p> <p>1 documents that have gone back and forth on this 2 issue. I'm -- surely -- I'm sure I have not seen 3 every document, because I don't believe Novartis 4 discovery is available in this case, so I haven't 5 seen a bunch of Novartis files. But certainly, I am 6 aware of some documents and some discussion, and -- 7 and those that I have seen indicated, generally, the 8 steps that Novartis took. 9 Q. So -- and hearing your counsel's 10 objection on foundation, I understand if you don't 11 know the answers to these questions. And if that's 12 the case, please let me know. 13 Novartis did not identify the potential 14 for NDMA formation based on analysis of the Valsartan 15 API chemical route of synthesis as documented in the 16 DMF, did they? 17 MR. VAUGHN: Object to form. 18 A. I can't answer that, actually, without 19 looking. I can't answer that. I don't know. 20 Q. And Novartis did not identify the 21 potential for NDMA formation as part of a risk 22 assessment it prepared on the Valsartan API, did 23 they? 24 MR. VAUGHN: Object to form. 25 Foundation.</p>	<p style="text-align: right;">Page 380</p> <p>1 described in other experts' reports. Maybe the 2 chemist's -- 3 Q. And -- 4 A. -- report. I'm not sure. 5 Q. And -- and just to say, Dr. Plunkett, 6 you don't know specifically how or why Novartis 7 eventually identified the NDMA in Valsartan API, do 8 you? 9 MR. VAUGHN: Object to form. 10 A. Well, I -- I can't -- I don't know -- if 11 you're asking why, I'm not in Novartis's head, so I 12 can't answer that. As far as what, I'm -- there's a 13 description of what they did, but I -- again, that 14 was beyond the scope of, I think, my -- of what I did 15 in terms of the opinions I formed because, to me, 16 that's more of an issue of -- maybe for the chemist 17 to describe what -- what they did in terms of the 18 methods they used, things like that. 19 Q. And I -- I think I understand. How 20 Novartis eventually identified and structurally 21 characterized NDMA is not part of the opinions that 22 you're offering in this case, correct? 23 A. That is true, that is not. I believe 24 that -- that may be someone else, but that's not me. 25 Q. And therefore, your opinion that the</p>

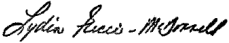
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<p style="text-align: right;">Page 381</p> <p>1 finished-dose manufacturers, including Teva, should 2 have done the same thing that Novartis did is only 3 based on the fact that you understand Novartis 4 eventually structurally characterized NDMA. Is that 5 fair?</p> <p>6 MR. VAUGHN: Object to form.</p> <p>7 A. I don't think I can answer that yes or 8 no. Can I explain or -- or can I ask you to clarify?</p> <p>9 Q. Let me try and ask a better question. 10 I -- I understand it's your opinion that 11 Teva and Torrent should have identified it based on 12 the fact that Novartis did. Is that fair?</p> <p>13 A. Novartis could, that's right, and they 14 did; yes, that's correct.</p> <p>15 Q. But you don't know how Novartis actually 16 structurally characterized and identified NDMA.</p> <p>17 A. Without going to look, I can tell you, 18 some of that is described. It talks about the 19 methods they used. That's in some of the documents, 20 but that was beyond the scope of, I think, what I was 21 asked to do in this case.</p> <p>22 I was not asked to, for example, 23 determine whether or not the chemical methods that 24 Novartis used were better or worse or -- you know, 25 I -- I mean, that -- that is all -- I think that's</p>	<p style="text-align: right;">Page 383</p> <p>1 of questions. You were very short, but yes, I do 2 recall.</p> <p>3 Q. I did not have much time. And you -- 4 you recall I represent the Torrent Defendants, 5 correct?</p> <p>6 A. Yes.</p> <p>7 Q. Dr. Plunkett, in your Materials Relied 8 Upon list, you list just shy of 30 documents that 9 were produced by Torrent, and one transcript from a 10 Torrent employee, correct?</p> <p>11 A. I don't know the exact number, but 12 that's probably true, yes. I think there's only one 13 transcript, that's for sure. I don't know if -- if 14 30 is accurate. But yes, there's certainly many, 15 many more documents with a ZHP Bates number on 16 there -- or Bates identifier on there.</p> <p>17 Q. Okay. And as part of that small set of 18 documents that you reviewed for Torrent, you reviewed 19 the -- some of the technical and quality agreements 20 between Torrent and ZHP, correct?</p> <p>21 MR. VAUGHN: Object to form.</p> <p>22 A. Certainly, some of those documents that 23 I have reviewed and relied upon are quality 24 agreements, yes. There's a paragraph in my report 25 where I think I cite to those.</p>
<p style="text-align: right;">Page 382</p> <p>1 sort of where -- where that goes, and so that's why 2 I'm hesitant to say anything more than what I've 3 already said. I think it is beyond the scope of what 4 I did. But I do know that there are documents that I 5 have reviewed that describe some of the -- the 6 details on how they did it.</p> <p>7 Q. And the specifics of that are beyond the 8 scope of your opinions in your report, correct?</p> <p>9 A. In terms of the opinions I had formed; 10 yes, that's correct. It wasn't -- it was not in -- 11 it was not something that I -- that I covered because 12 it's my -- in my view, that would be an issue for a 13 chemist to cover, for example, or someone else may 14 have been asked to do that, but that wasn't something 15 I was asked to do.</p> <p>16 MR. HARKINS: Thank you, Dr. Plunkett. 17 Those are all the questions that I have for you 18 today. I believe counsel for Torrent is gonna have 19 some follow-up as well.</p> <p>20 MR. VAUGHN: Thanks, Steven.</p> <p>21 RE-CROSS-EXAMINATION BY MS. NAGEL: 22 Q. Good morning, Dr. Plunkett. Do you 23 remember we spoke a few weeks ago during the first 24 part of your deposition?</p> <p>25 A. Yeah. I think you just asked a couple</p>	<p style="text-align: right;">Page 384</p> <p>1 Q. And the quality agreement establishes 2 what parts of the DMF are gonna be shared with 3 Torrent, correct?</p> <p>4 MR. VAUGHN: Object to form.</p> <p>5 A. I don't know if that's addressed. I -- 6 I believe the quality agreement -- the part that I 7 talk about talks about who's respons- -- who's 8 responsible for what, but if you want me to pull it 9 up.... I can't answer that without looking.</p> <p>10 Q. Dr. Plunkett, you didn't actually review 11 the parts of the DMF that were shared with Torrent, 12 did you?</p> <p>13 MR. VAUGHN: Object to form.</p> <p>14 Argumentative.</p> <p>15 A. I did not review the entire Drug Master 16 File; that is correct. And I -- and I can't tell you 17 which parts were shared, so -- without -- so I don't 18 think I have information to answer that. I don't 19 think I can answer that.</p> <p>20 Q. Okay. And Dr. Plunkett, what documents 21 did you rely on in forming -- or what Torrent 22 documents did you rely on in forming your opinion 23 that Torrent should have obtained full access to 24 ZHP's DMF?</p> <p>25 A. Well, I don't think I'm necessarily</p>

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<p>Page 385</p> <p>1 relying on Tor- -- well, I'm relying on the -- the 2 documents that -- that show that Torrent and ZHP had 3 an agreement to -- to exchange -- to set -- they 4 had an -- they had an agreement to buy product from 5 ZHP. So that part of the -- the agreement ties them 6 together as -- as the supplier for the finished-dose 7 manufacturer.</p> <p>8 Beyond that, my opinions that I have 9 expressed are based upon the regulatory requirements 10 for -- as a finished-dose manufacturer to ensure that 11 their product is compliant with GMP, the -- and my 12 experience and training.</p> <p>13 And then I think, as I have said, as I 14 just discussed with Mr. Harkins as it relates to 15 Teva, those -- those same opinions would hold. It's 16 the idea that what regulations put the onus on the 17 finished-dose manufacturer for the product they sell. 18 The guidance describes, in fact, that the 19 finished-dose manufacturer is supposed to take steps 20 to validate the -- the product that comes from their 21 supplier routinely. It's not something that only is 22 done once. It has to be done continually over time 23 to -- to make sure -- to ensure that the product 24 remain as it did the first day they moved -- shipped 25 the batch that they initial- -- they initially may</p> <p>Page 386</p> <p>1 have used for their initial validation exercise, so 2 they have other responsibilities.</p> <p>3 So I think the majority of my opinions 4 would -- the majority of the information that I have 5 relied upon to form that opinion would be based upon 6 the general regulation, my experience and training, 7 as well as them -- the agreement that shows that the 8 two parties were, indeed, engaged in a relationship 9 of an API being bought from ZHP and that Torrent was 10 the finished-dose manufacturer and the holder of the 11 ANDA.</p> <p>12 Q. So to confirm, you're not relying on any 13 documents -- any Torrent documents that establish 14 what information Torrent had from the DMF in forming 15 that opinion, correct?</p> <p>16 MR. VAUGHN: Object to form.</p> <p>17 A. I don't know. I mean, I'd have to go 18 back and look if any of the documents that I have 19 discuss that. That's why I think I started -- when 20 you asked the question before this one, I think I 21 said I'd have to -- I don't know. I'd have to look 22 whether or not the quality agreement addresses that 23 specific issue. I can't answer that without looking.</p> <p>24 Q. And Dr. Plunkett, I believe you 25 testified a few minutes ago that you did not review</p>	<p>Page 387</p> <p>1 ZHP's DMF or what parts were made available to 2 Torrent. Is that right?</p> <p>3 A. I said I -- I think I -- I think what I 4 said was I did not review the entire DMF. I did not. 5 And I'm not -- and also, right as I sit here, I'm not 6 aware of any document that tells me exactly what they 7 were made -- what was made available to them. But 8 certainly, that is -- I have seen discussions of 9 their ability to be able to reference the DMF. So 10 again, I can't answer your question fully without 11 looking at the Torrent documents I have. I don't 12 recall one, though.</p> <p>13 MS. NAGEL: Okay. Mr. Vaughn, can I 14 have like five minutes?</p> <p>15 MR. VAUGHN: For a break?</p> <p>16 MS. NAGEL: Yes, please.</p> <p>17 MR. VAUGHN: Yeah, Of course.</p> <p>18 THE VIDEOGRAPHER: The time is 9:55. 19 We're going off the record. 20 (Break: 9:55 a.m. Central Time.) 21 (Resume: 10:01 a.m. Central Time.) 22 THE VIDEOGRAPHER: The time is 10:01. 23 We're back on the record.</p> <p>24 MS. NAGEL: So Dr. Plunkett, that is all 25 the questions I have for you, and I think Defendants</p> <p>Page 388</p> <p>1 are just going to reserve the remainder of their time 2 for any recross.</p> <p>3 MR. VAUGHN: I have no questions, so I 4 think we're done.</p> <p>5 THE VIDEOGRAPHER: Great. The time is 6 10:01. This ends today's deposition. 7 (Proceedings concluded at 10:01 a.m. 8 Central Time.) 9 ----- 10 J U R A T 11 12 I, LAURA M. PLUNKETT, Ph.D. DO HEREBY 13 CERTIFY that I have read the foregoing transcript of 14 my deposition testimony. 15 16 _____ 17 LAURA M. PLUNKETT, Ph.D. 18 19 20 SWORN TO AND SUBSCRIBED 21 BEFORE ME THIS _____ 22 DAY OF _____ 23 2023 24 _____ 25 Notary Public</p>
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<p>1 ATTACH TO DEPOSITION OF: IN RE: VALSARTAN, LOSARTAN 2 AND IRBESARTAN PRODUCTS LIABILITY LITIGATION 3 4 DATE TAKEN: Friday, February 10, 2023 5 6 ERRATA SHEET 7 8 INSTRUCTIONS: After reading the transcript of testimony, please note any change, 9 addition or deletion on this sheet. DO NOT make any marks or notations on the transcript itself. 10 Please sign and date this errata sheet and return it to the court reporter whose name is 11 shown below. 12 13 PAGE LINE CHANGE 14 _____ 15 _____ 16 _____ 17 _____ 18 _____ 19 _____ 20 _____ 21 _____ 22 _____ 23 _____ 24 _____ 25 _____</p>	<p>Page 389</p>
<p>1 CERTIFICATE 2 3 I, LYDIA F. McDONNELL, a Certified 4 Shorthand Reporter and Notary Public of the State of 5 New Jersey, do hereby certify that prior to the 6 commencement of the examination, LAURA M. PLUNKETT, 7 Ph.D. was duly sworn by me to testify the truth, the 8 whole truth and nothing but the truth. 9 I DO FURTHER CERTIFY that the foregoing 10 is a true and accurate transcript of the testimony as 11 taken stenographically by and before me at the time, 12 place, and on the date hereinbefore set forth. 13 I DO FURTHER CERTIFY that I am neither a 14 relative nor employee nor attorney nor counsel of any 15 of the parties to this action, and that I am neither 16 a relative nor employee of such attorney or counsel, 17 and that I am not financially interested in the 18 action. 19 20 21  Notary Public of the State of New Jersey 22 License No. 30XI00155900 23 My Commission expires June 30, 2024 24 Dated: February 16, 2023 25</p>	<p>Page 390</p>

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

VERITEXT LEGAL SOLUTIONS
COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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